

Today's Program

Challenges and Opportunities in Peer Review

Critical Changes in Peer Review

The Study Section Chairs as Effective Partners



Challenges and Opportunities in Peer Review

A Vision for Ensuring Its Strategic National Value

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center for scientific review

Study Section Chairs Cleveland, OH July 30, 2010

National Institutes of Health

U.S. Department of Health and Human Services



NIH Peer Review

- > Peer Review's Strategic, National Value
- > USA Support for Biomedical Research
- > NIH and Peer Review
- > The Drivers for Change
- > Enhancing Peer review: CSR
- > Enhancing Peer review: Corporate NIH
- > Peer Review's Strategic, National Value



30 Years of Medical Innovation

- MRI and CT Imaging
- ACE inhibitors
- Angioplasty
- Statins
- Mammography
- Coronary Interventions
- H inhibitors and H2 Blockers
- Antidepressant
- Cataract and Lens Replacement
- Ultrasound Imaging

- Asthma Treatment
- Cardiac Enzymes
- Fluoroquinolones
- Hypoglycemic Agents
- HIV Testing and Intervention
- Tamoxifen
- PSA
- H. Pylori Test and Treatment
- Cephalosporins
- Calcium Blockers
- Conscious Sedation



NIH Support to Nobel Prizes Who Later Received Nobel Prizes in Physiology/Medicine or Chemistry





Why Has The U.S. Biomedical-Behavioral Research Been So Successful?

- Equation of unique dynamic partnershaps -- through NIH
 ween Governmer diagram academic medical schools
- USF, Son not seek son til til til
- 10% I r Is to he shorth a classification in the contraction of the programmer of the contraction of



The Rules and the Results of the Process

- NIH Pays Science not directly Scientists or Institutions
- Researchers are "Contractors" who bid in an open competition
- Peer Review is the judge of the competition
- Universities and Research Institutions receive funds only to the extent they have competitive Faculty

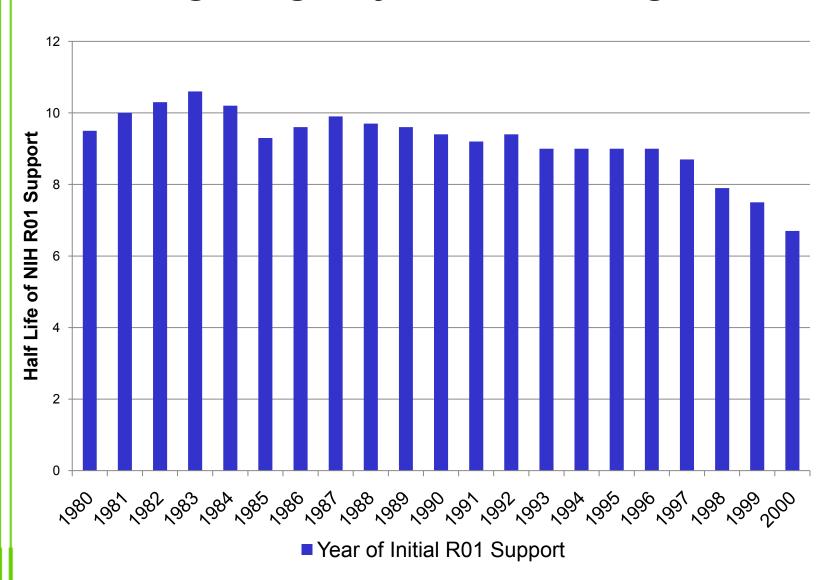


Major Differences Between Europe and U.S. In Funding Biomedical Research

| | Others | U.S. |
|-------------------------|---|---|
| Organization | Ministry of university, science/research/education | Department Health and Human Services |
| Goal | Promote biomedical research Provide employment for scientists | Promote cures Reengineer medicine |
| How funds are allocated | Large entitlement to universities, research centers Small fraction through peer review to researchers | 100% through peer review to researchers |



Funding Longevity of NIH Investigators





The Influence of NIH Peer Review in the USA

For U.S. Universities and Academic Medical Centers

- Finances of Universities and Research Hospitals
- The promotion committee of medical schools
- The prestige of universities and medical schools

For People and for Public Health

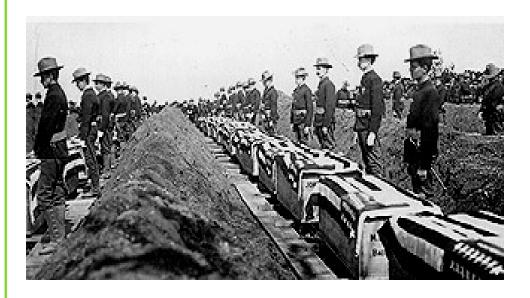
- Which research is done
- Which cures people get



How Federal Support for Biomedical Research Developed in the USA



The First Peer Review

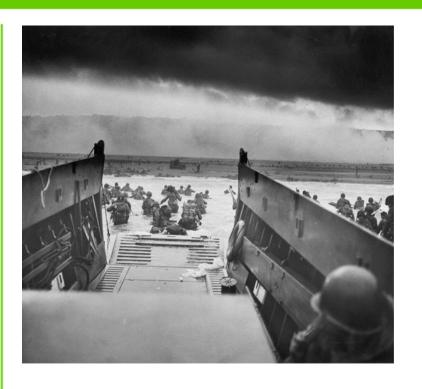


Responses to Yellow Fever

1879

- Yellow fever destroyed the Mississippi Valley
- A \$30,000 bid (RFA) from the US Army for Universities
- 1st peer-reviewed applications for research.





Responses to World War II: The Race for Penicillin

- President Roosevelt set up the National Defense Research Committee.
 - Awarded contracts for rapid production projects
 - Identified 700 universities for future contracts

1942

- Medical Research funding grew from \$2.3 million to \$7.5 million, rating applications with an "A", "B", or "C".
- 21 penicillin production plants (led to a 97% survival rate for wounded soldiers.)



The Fundamental Tenets for NIH (1946)

- The only possible source for adequate support of our medical research is the taxing power of the federal government.
- The federal government and politicians must assure complete freedom for individual scientists in developing and conducting their research work.
- 3. Reviews should be conducted by outside experts essentially without compensation.
- 4. Program management and review functions should be separated.



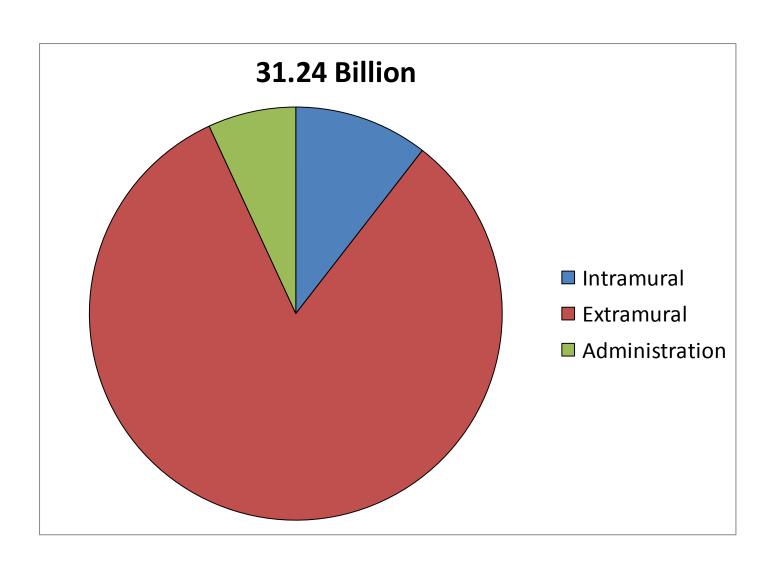
Surgeon General Thomas Parran, Jr.



NIH and Peer Review at CSR



FY 2010 Enacted NIH Budget





Extramural Grants By Research Institutions



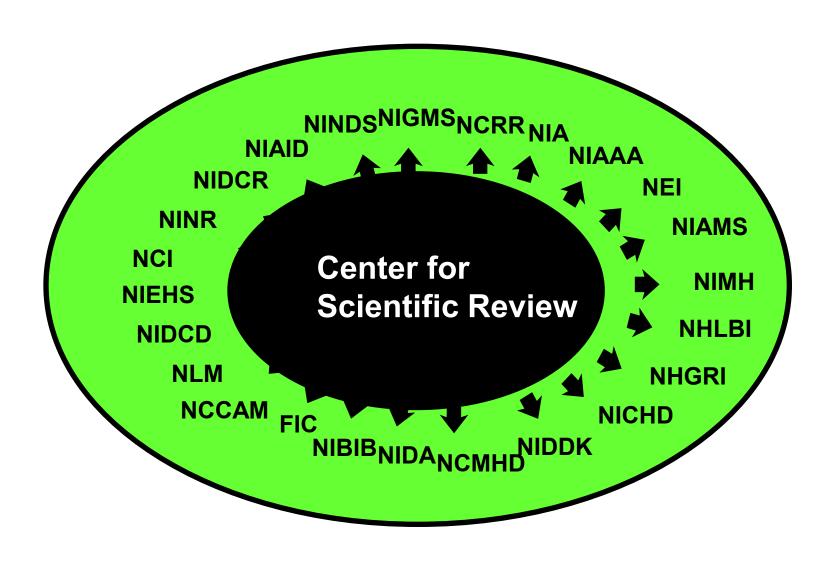


NIH Grants to Foreign Institutions -- 2009

| Country | Award Totals, in Millions |
|-----------------|---------------------------|
| CANADA | \$52.7 |
| SOUTH AFRICA | \$51.3 |
| UNITED KINGDOM | \$22.6 |
| AUSTRALIA | \$13.9 |
| GERMANY | \$9.3 |
| BRAZIL | \$7.3 |
| SWITZERLAND | \$7.0 |
| FRANCE | \$5.1 |
| INDIA | \$4.9 |
| CHINA | \$4.8 |
| Other Countries | \$41.9 |
| Total | \$220.7 |



24 NIH Institutes and Centers Fund Grants





The Basic Operating Principles

NIH has ownership of the process

 The Scientific Review Officer nominates the review panel, assigns applications and is responsible for the meeting

The study section (SRG, review panel) has ownership of the science.

- Is composed of the best and most experienced scientists in the field). Usually 20 are permanent members, serving 4 years 3 times/year and 10 are ad hoc
- CSR have over 800 study sections reviewing different biomedical behavioral science



CSR Mission Statement

To see that NIH grant applications receive fair, independent, expert, and timely reviews – free from inappropriate influences – so NIH can fund the most promising research.



CSR Peer Review: 2008

- 77,000 applications received
- 16,000 reviewers
- 1,600 review meetings
- 240 Scientific Review Officers



CSR Peer Review: 2009

115,000

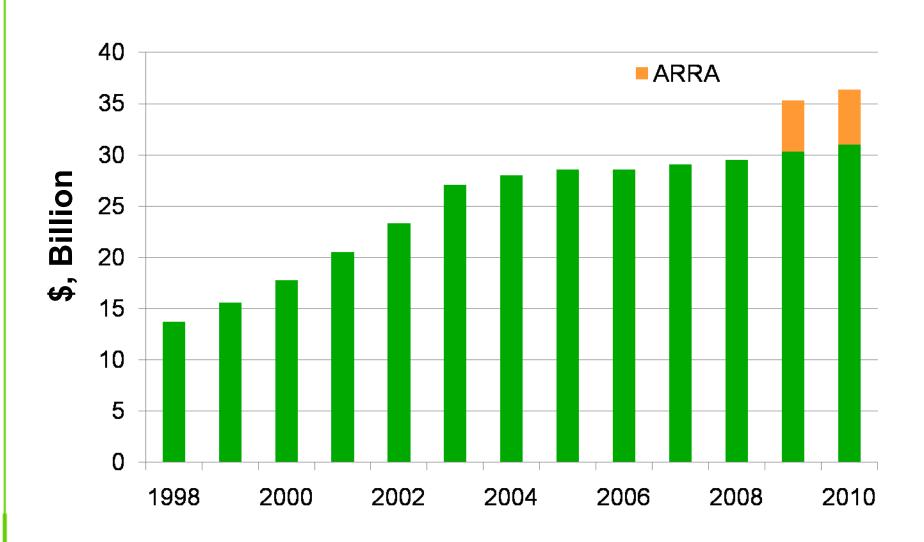
- 77,000 applications received
- 16,000 reviewers 38,000
- 1,600 review meetings 2,500
- 240 Scientific Review Officers



The Drivers for Change



1st Driver: The NIH Budget



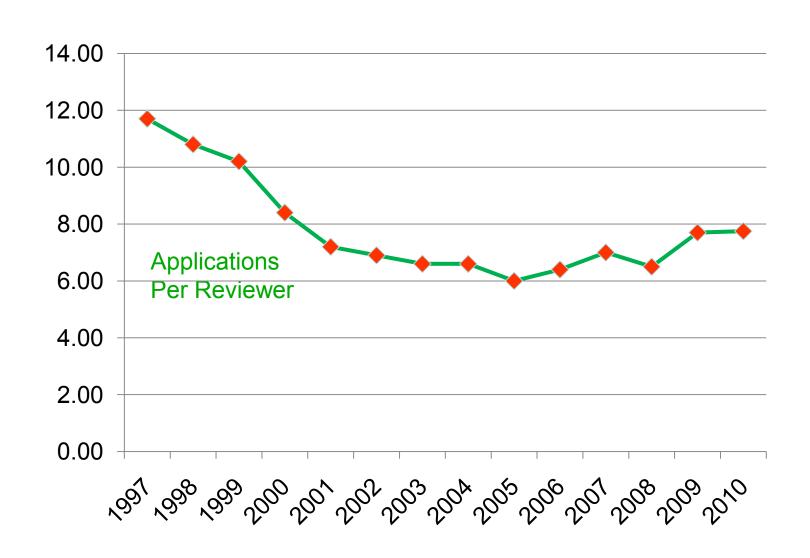


2nd Driver: Number of Applications



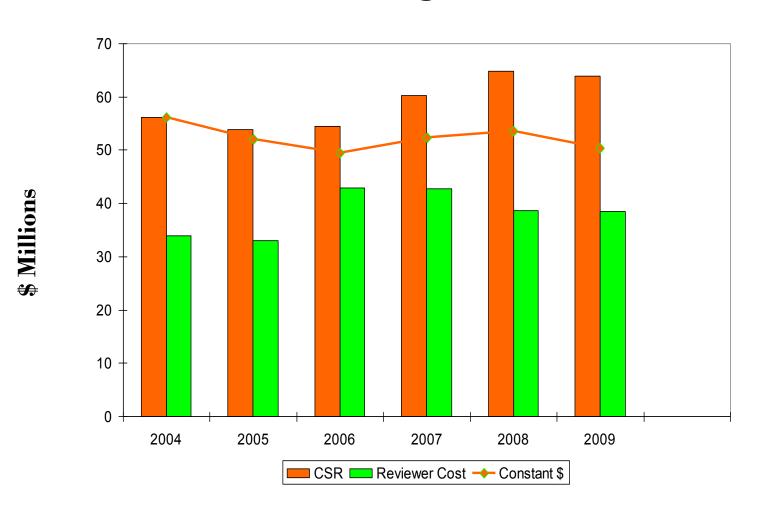


3rd Driver: Reviewer's Load





4th Driver: CSR Budget



Cost of Peer Review, including travel and small honorarium for 20,000 Reviewers is 0.4-0.6% of the funds requested



Annual Savings in Reviewers' Expense Budget

- Non-refundable tickets with one possible change
 - \$17 million
- 3,000 fewer reviewers
 - \$3 million
- 20% reviews using electronic platforms
 - \$6 million
- One meeting a year on the West Coast
 - \$1.8 million



5th Driver: One Review Platform for 63 years

The First NIH Study Section A NIH Study Section Today

1946 2008

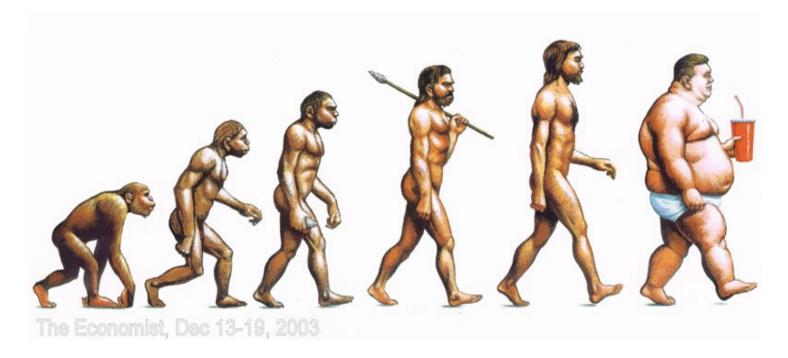






6th Driver: The World Is Changing

- The way research is done has changed
- The diseases of Americans have changed



The Land of the Free, The Home of the Fries



CSR's Efforts to Enhance Peer Review



Major Complaints About NIH Peer Review

- The process is too slow
- There are not enough senior/experienced reviewers
- The process favors predictable research instead of significant, innovative, or transformative research
- The time and effort required to write and review are a heavy burden on applicants and reviewers

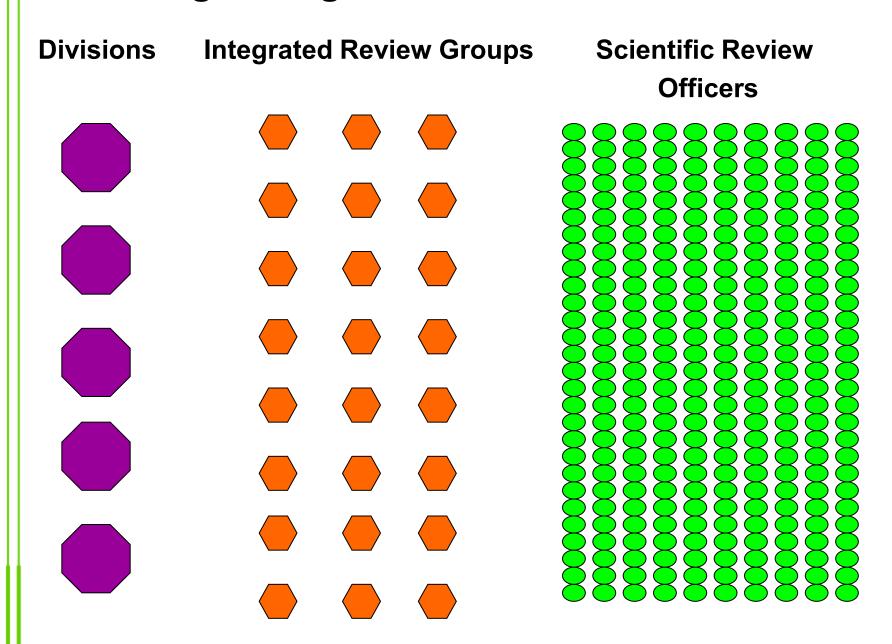


CSR's Efforts to Enhance Peer Review

- Reorganizing CSR and Recruiting Staff
- Rewriting Study Section Guidelines
- Improving Study Section Alignment
- Assigning Applications more Accurately
- Reviewing Clinical Research
- Shortening the Review Cycle
- Advancing Additional Review Platforms
- Recruiting the Best Reviewers

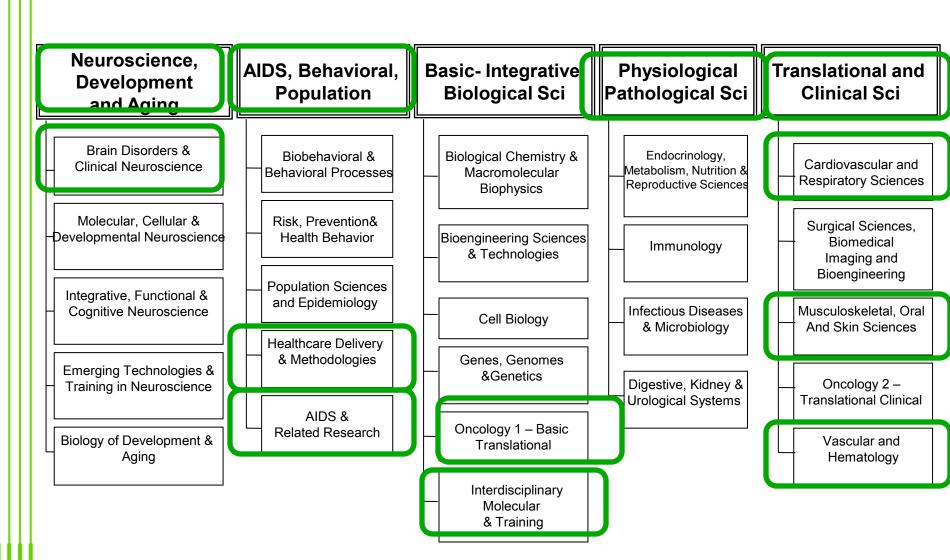


1. Reorganizing CSR





1. Reorganizing CSR





2. Revising Study Section Guidelines

- Cellular Signaling and Regulatory Systems
- [Roster]
- The Cellular Signaling and Regulatory Systems (CSRS) study section reviews applications that
 focus on the initiation and execution of programs that control cellular homeostasis and
 physiology. A distinguishing characteristic of these applications is an emphasis on signaling
 networks and the coordination of processes related to cell proliferation, survival, and growth.
- Cell cycle regulation, mitosis, meiosis, checkpoint controls and regulation by ubiquitination
- Proteolytic mechanisms associated with cell cycle, senescence and death
- Programmed cell death and apoptosis, particularly their regulation in the context of stress, growth, and transformation.
- Proliferation and growth control by the nucleus; signaling pathways regulating transcription
- Integrative cell physiology, e.g., stress, clocks, cellular modeling; cell differentiation and transformation
- Basic studies of cytokine signaling
- Application of state-of-the-art technologies such as imaging and computational modeling of cellular signaling networks
- Study sections with most closely related areas of similar science listed in rank order are:
- Molecular and Integrative Signal Transduction
- Intercellular Interactions
- Membrane Biology and Protein Processing
- Molecular Genetics A
- Molecular Genetics B



3. Improving Study Section Alignment

- Input from the community
- Internal IRG reviews
- Open Houses
- PRAC



4. Assigning Applications Accurately





CSRRFebbyaary2002007



4. Assigning Applications Accurately

Retooled for electronic submission

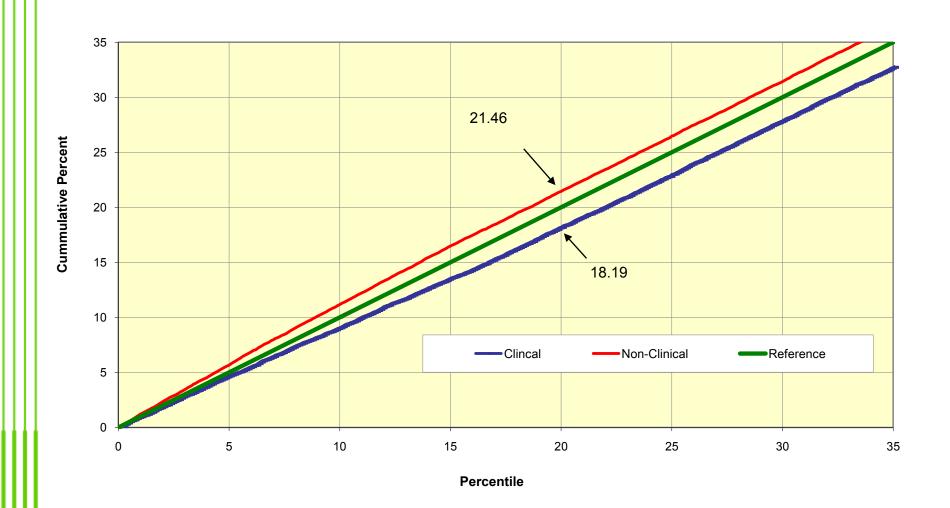
Applications are now submitted electronically

Assign applications using text fingerprinting, and text mining programs



5. Reviewing Clinical Applications

2004-2007 All Clinical vs. All Non Clinical R01s





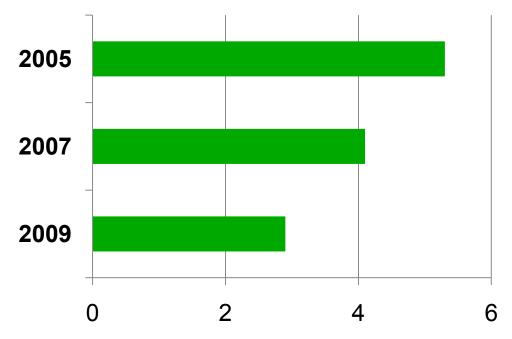
5. Reviewing Clinical Applications

| R01 Applications 2005-2008 | Clinical | Non Clinical |
|----------------------------|----------|-----------------|
| Type 1 New Investigator A0 | 5.4% | 5.9% |
| Type 1 Established A0 | 10.2% | 10.2% |
| Type 2 A0 | 8.6% | 17.0% |
| | | |

Significant Numbers of Clinical Grantees Are Not Submitting Renewal Applications



6. Shortening the Review Time



Months: Submission to Posting Summary Statements

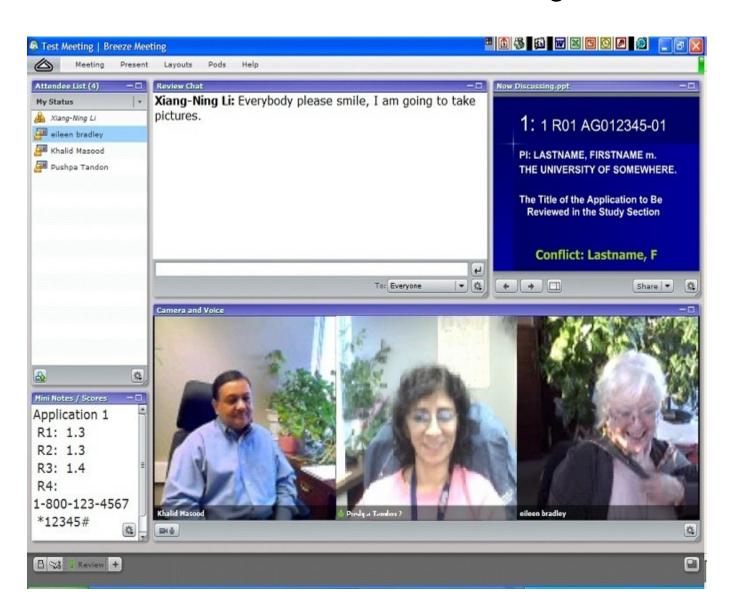
To enable resubmission, when doable and desirable, 4 months earlier than in the past.



- Additional Review Platforms Help Recruiting Reviewers
- Electronic Review Modes Reduce Travel
- Electronic Reviews
 - Telephone Assisted Meeting
 - Video Assisted Meeting
 - Internet Assisted Meeting (previously AED)



What It Looks Like: Video Assisted Meeting





What It Will Looks Like: Video Assisted Meeting





7. The First Telepresence Study Section





What It Looks Like:

Internet Assisted Meeting (previously AED)



0

0

6

5

4



REAGAN, RONALD

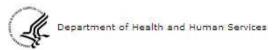
LINCOLN, ABRAHAM

HOOVER, HERBERT

1P31AED1111111-01-704

1P31AED111111-01-690

1P31AED111111-01-695





Reviewer 2

Reviewer 3

1

3

4



7. Advancing Additional Review Platform What It Looks Like: Internet Assisted Meeting (previously AED)

Secondary reviewer

I agree with the Primary review about the significane of this research. The design of the experiments is thorough, and the application as a whole is clearly written. I am very impressed that he has recruited Dr. Briere as a co-PI. His expertise in microdialysis will be a great benefit to the proposal

I did have some concern over the small sample size that was used for the preliminary data (n=3). This important because the hypotheses for specific aim 1 is based on these data, and if the results are not significant then it could alter the experiments. However the PI does point this out, and it is only a minor concern.

hendrixji | 1/18/2010 9:22:29 AM

Innovation

I am concerned that although the combination of techniques is innovative, the results of this combination will be of little impact in the field. Recent publication by Smith from the University of Nowhere used a similar approach and the results were not as impressive (Smith et al. 2010 – J. of Immag. Res. 23: 2456-2462).

guthriear | 1/18/2010 9:06:41 AM

Innovation

I agree with Jon. This is an innovative combination of approaches.

butterfieldp | 1/18/2010 8:51:29 AM

Innovation

While none of these approaches by themselves are particularly innovative, their aggressive combination is state-of-the-art and I am unaware of this approach used before in the field.

baezio | 1/18/2010 8:22:28 AM

Application summary and evaluation

As the primary reviewer I will provide a brief overview of the application. This application proposes to use in vivo electrophysiological recording and behavior tests to measure the effects of cocaine self-administration and withdraw on dopaminergic activity. The experiments will use a rodent model of self-administration.

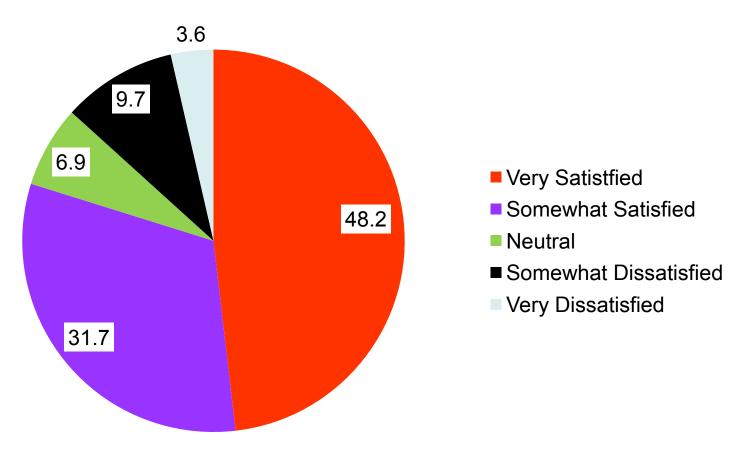
The significance of the proposal is high since the experiments will examine important questions in the field of drug abuse. The investigator clearly has the expertise to perform the experiments, and his publication rate has been impressive in the last few years. In addition the hypotheses are novel and well thought out.

There are some concerns with the specific antagonists that will be used in Aim 2. However this concern is minor and does not decrease the high level of enthusiasm that I have for this proposal.

butterfieldp | 1/17/2010 3:40:09 PM



Advancing Additional Review Platforms Reviewer Satisfaction with Internet Assisted Meeting



http://www.csr.nih.gov/EvaluationReports/



7. Advancing Additional Review Platforms Cost Comparison of Review Platforms

| | Phone | Internet | Video | Face to Face |
|------------------|-------|----------|-------|--------------------|
| Cost/application | 25 | 107 | 237 | 867 |
| Cost/reviewer | 31 | 100 | 292 | 1767 |

Not including honoraria for reviewers

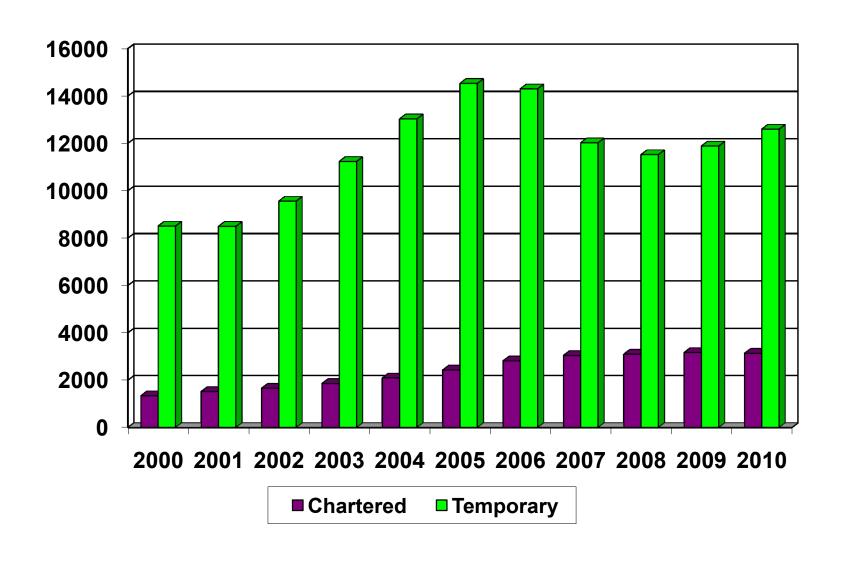


Editorial Board Review

- Complex Science
- Small Business
- TR01
- Several ARRA Mechanisms

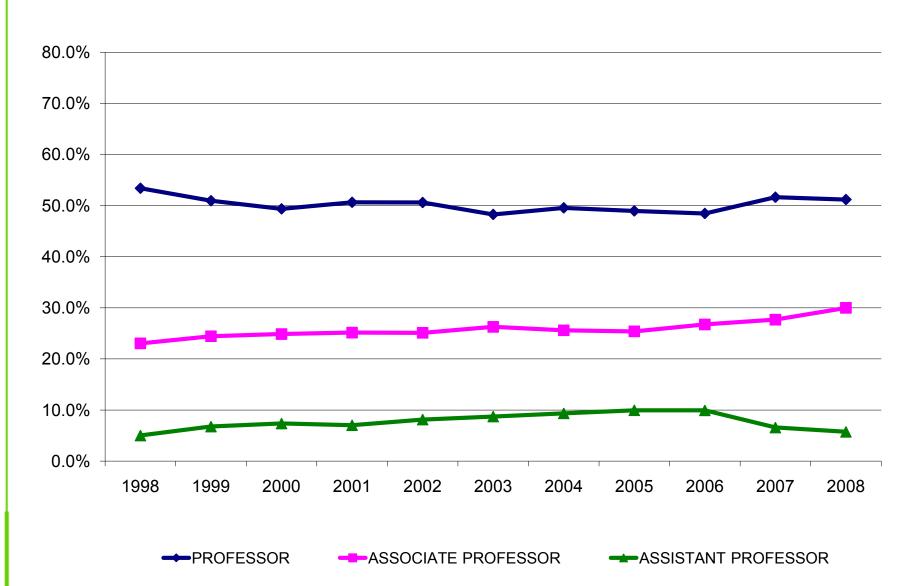
College of Reviewers







Academic Rank of ALL CSR Reviewers





Some Successful Strategies

- •Move a meeting a year to the West Coast
- Additional review platforms
- Develop a national registry of volunteer reviewers
 - Searchable database with 5,000 reviewers
- Provide tangible rewards for reviewers
 - No submission deadlines for chartered members
 - of study sections (effective February 2008).
- Provide flexible time for reviewers
 - •Choice of 3 times/year for 4 years or
 - •2 times/year for 6 years



Expansion of No Submission Deadlines

Present (since February 2008)

Chartered Study Section Members

o CSR

o Other ICs 1012

4,139

1,976

Planned for 2009

Frequent Reviewers* 1323

BSC regular members 260

NAC members 393

* 6 meetings/last 18 months

3127



9. Miscellaneous

- Enlarging Published Rosters for Small SEPs
- Pull Down Menu for SS Selection and Application Template
- Circumventing Length of Applications
- Evaluating New vs A2 Applications
- Abolishing CDs
- Sun Setting Additional Material
- Requiring Review Service
- Participating by Phone
- Evaluating Peer Review



Enhancing Peer ReviewThe NIH Director's Recommendations



Corporate NIH: Enhancing Peer Review

The Charge from Dr. Zerhouni:

"Fund the best science, by the best scientists, with the least administrative burden..."

Two advisory committees to the NIH Director

http://enhancing-peer-review.nih.gov



The Process

Diagnostic

Design Implementation Plan Begin Phased Implementation of Selected Actions

June 2007 - Feb. 2008

March 2008 – June 2008

September 2008



1. Review Highly Transformative Research

OD Transformative RO1 (T-RO1)

- Awards once a year, funding for 5 years
- 8-page application
- 740 submitted, 720 reviewed
- 42 funded (\$ 32 million)

Editorial Board Review

- Initial scoring based on innovation and potential science transformation by a small study section of distinguished, broad-science reviewers (the editors)
- Specific science reviewed by appropriate reviewers (subject experts-the editorial board)
- Final ranking by the editors



2. Early Stage Career Investigators

Definition of New Investigator:

 Not previously competed successfully as PD/PI for a significant NIH independent research award.

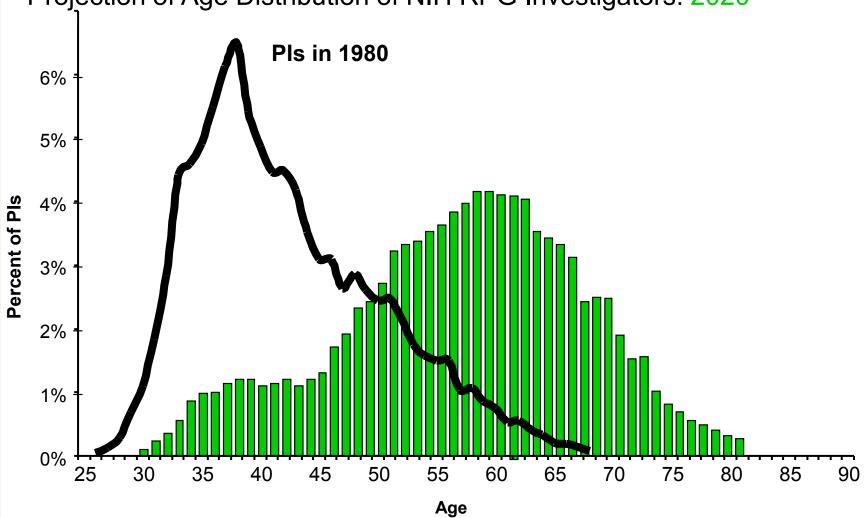
Definition of Early Stage Investigator:

- Within 10 years of completing terminal research degree or within 10 years of completing medical residency (or the equivalent).
- Applies only to R01 applications



2. Early Stage Career Investigators

Projection of Age Distribution of NIH RPG Investigators: 2020





2. Early Stage Career Investigators

Funding for New Investigators and ESI

 The NIH corporate policy is to fund R01s of New Investigators and ESIs at different paylines

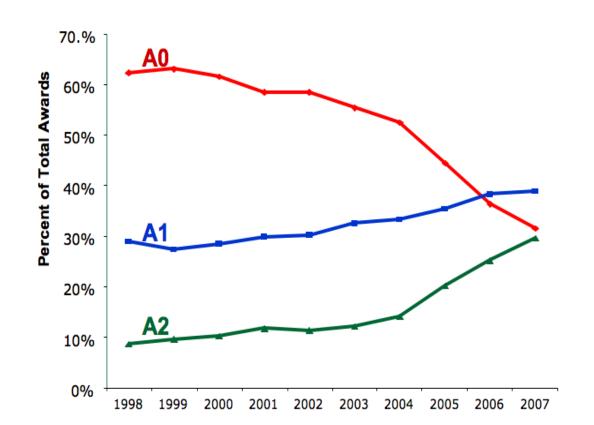
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3 Paylines for R01s



3. Funding the Best Research Earlier and Reducing the Burden on Applicants, Reviewers, and Institutions

- More flexible deadlines
- Abolish A2 applications





4. Improve Quality and Transparency of the Peer Review Process

Shorten applications, aligning with review criteria

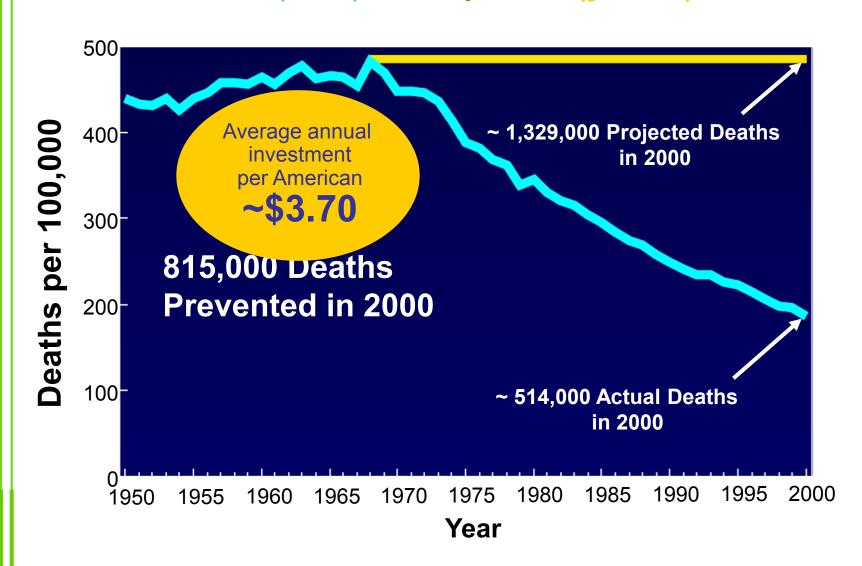
 Shorten summary statements, follow template for each criteria

Change the rating system



Coronary Heart Disease

Age-Adjusted Death Rates in U.S.: Actual (blue) vs. Expected (yellow)



National International Hope



Critical Changes in Peer Review

The Stimulus and Beyond

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center for scientific review

Orientation for Study Sections Chairs July, 2010

National Institutes of Health

U.S. Department of Health and Human Services



Recent and Future Peer Review Changes

Changes occurred at the last meeting (May June 2009):

- Scores 1-9
- Assigned reviewers score each criteria
- Shorter summary statement, with boxes for each criteria
- Discussion of new investigators first
- Scores of individual criteria given to all applicants
- Discussed applications will receive additional overall impact score
- Changes occurring in 2010:
- Shorter application (12 pages for R01) designed to match scoring criteria



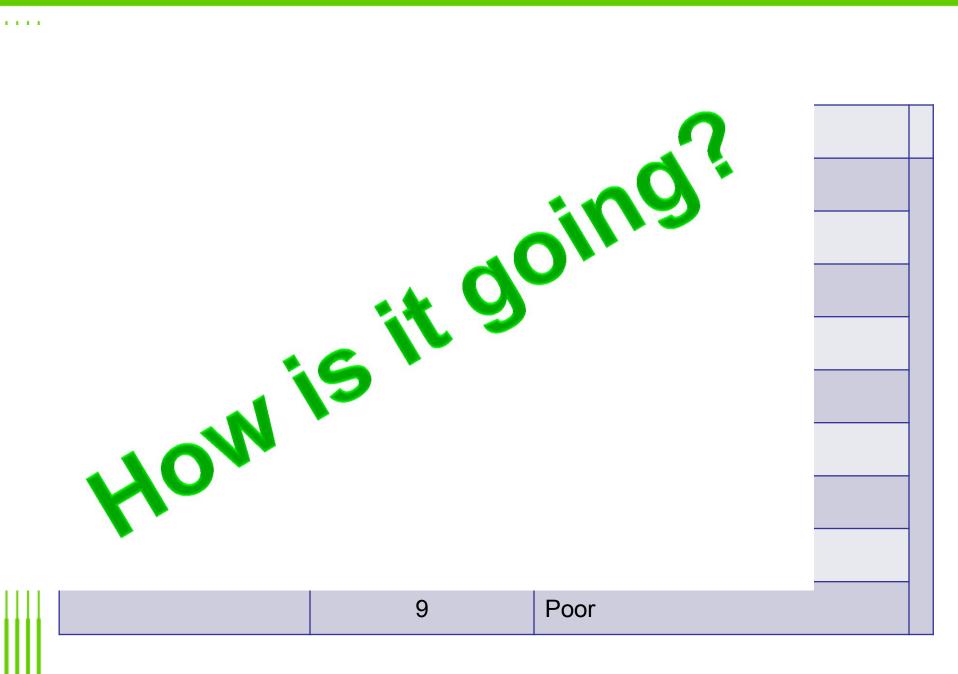






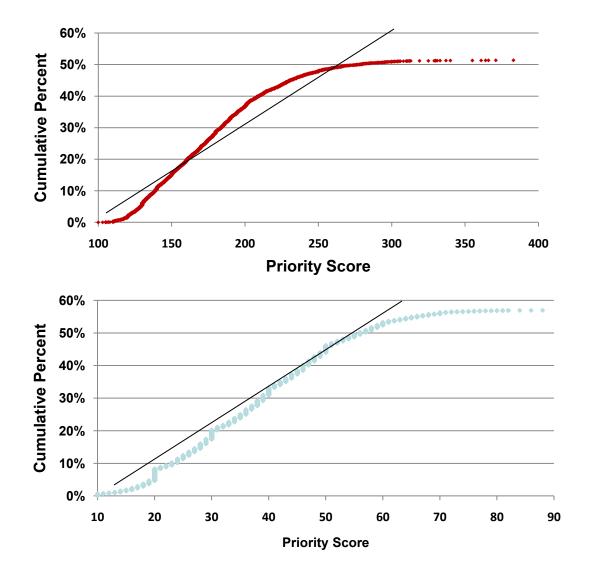
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3. Scoring Priority Scores of R01 and R21 Reviewed by CSR

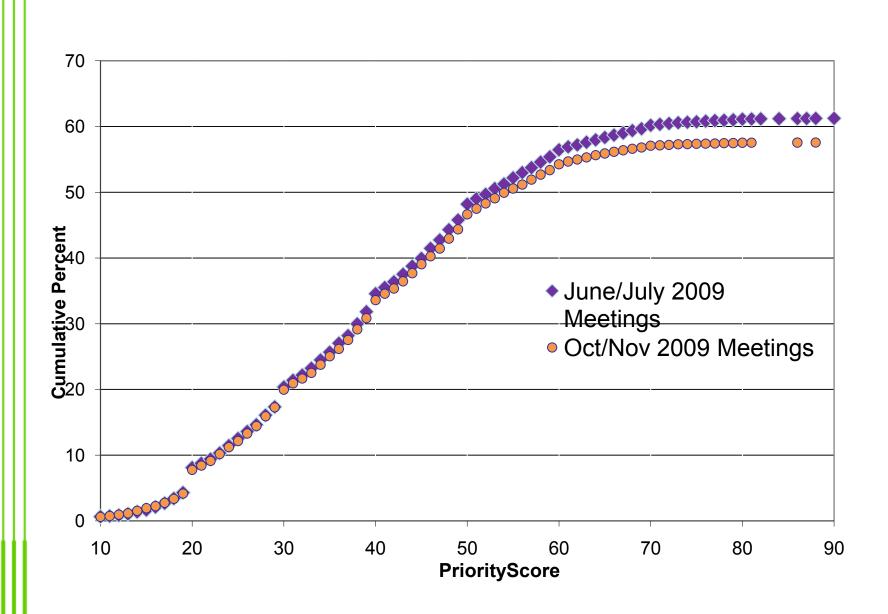


June 2008

June 2009



Priority Scores of R01 and R21 Reviewed by CSR





of



4. Order of Review, Tool for NIH Program









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7. Shorter Page Limit Guide

| Section of Application | Page Limits |
|---|----------------|
| Introduction for Resubmission Application | 1 |
| Specific Aims | 1 |
| Research Strategy: R03, R13/U13, R21, R36, R41, R43, Fellowships (F), SC2, SC3 | 6 |
| Research Strategy: R01, single project U01, R10, R15, R18, U18, R33, R24, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1 | 12 |
| Biographical Sketch | 4 |

Page limits may vary for other funding mechanisms.

Check: http://enhancing-peer-review.nih.gov/page_limits.html



Links of Interest

Enhancing Peer Review: The NIH Announces Enhanced Review Criteria for Evaluation of Research Applications Received for Potential FY2010 Funding

http://grants.nih.gov/grants/guide/notice-files/not-od-09-025.html

Page Limits: http://enhancing-peer-review.nih.gov/page_limits.html

Human Subjects: http://grants.nih.gov/grants/policy/hs/index.htm

Vertebrate Animals: http://grants.nih.gov/grants/olaw/olaw.htm

SF424 guidelines for submission:

http://grants.nih.gov/grants/funding/424/index.htm

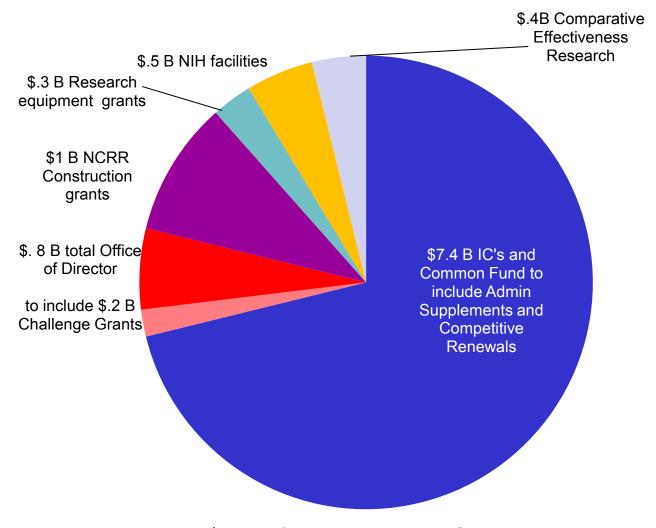
For any other questions contact your SRO



ARRA: The Stimulus



The Stimulus



ARRA: \$10.4 B for 2 years through September 2010

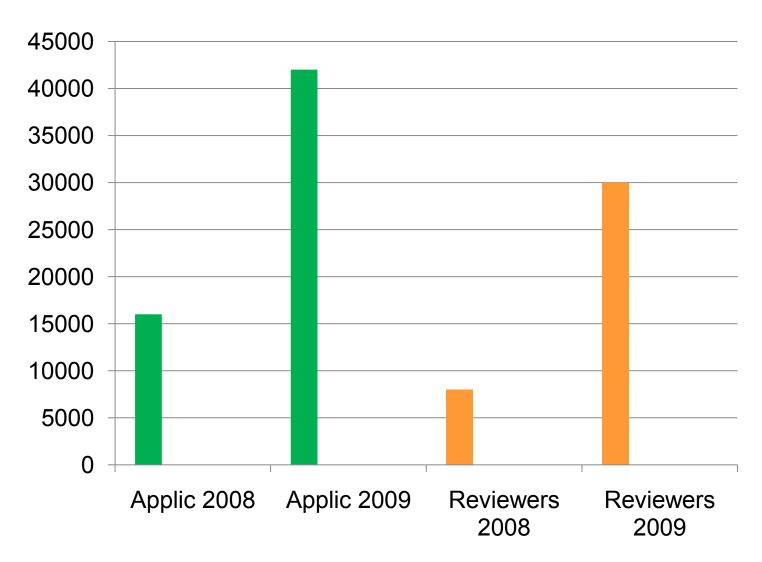


ARRA 2009

| RFA | APPLICATIONS | REVIEWERS | FUNDED |
|--------------------------|--------------|-----------|--------|
| Challenges | 20,981 | 15,153 | 838 |
| Competitive Revisions | 2,136 | 5,050* | 427 |
| GO Grants | 2,411 | 4,300* | 378 |
| High End Instrumentation | 853 | 2,328 | 26 |
| Small Business | 1,401 | 472 | 30** |
| AREA | 1,041 | 360 | 30** |
| Community Infrastructure | 533 | 560 | 30** |
| TOTAL | 29,356 | 28,223 | |



Applications Reviewed and Reviewers Used by CSR in June 2008 and 2009





The Way We Did It

To achieve great things, three things are needed: a plan, great people and not quite enough time

adapted from Leonard Bernstein

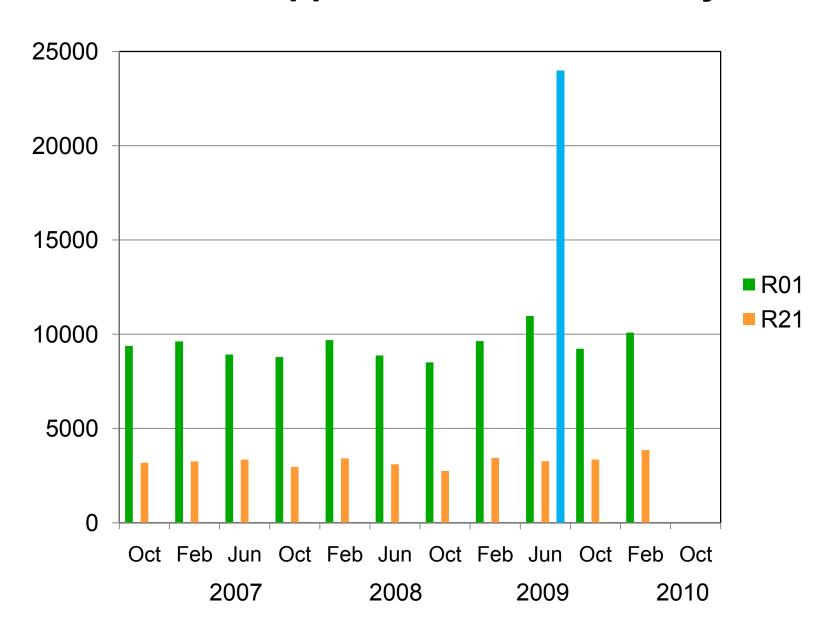


This is CSR



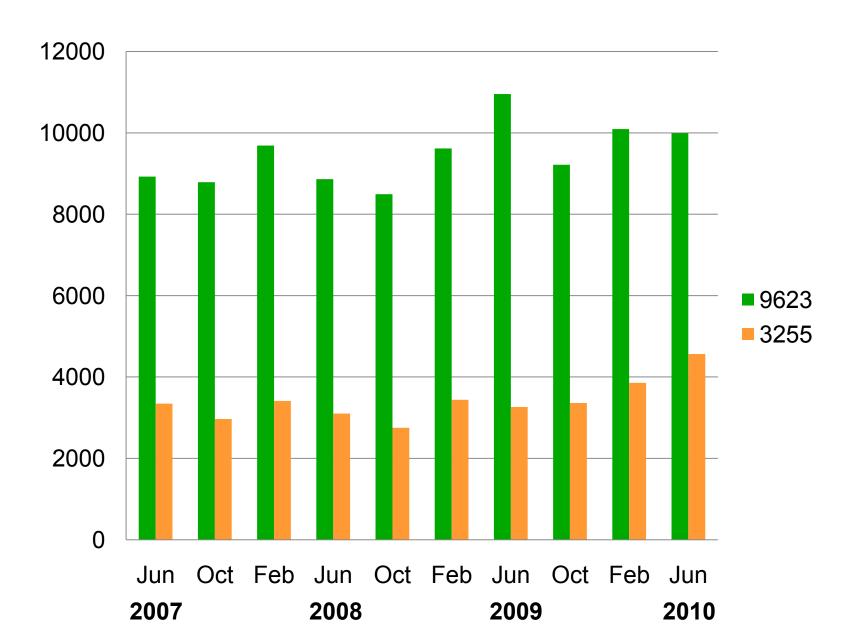


R01 and R21 Applications Reviewed by CSR



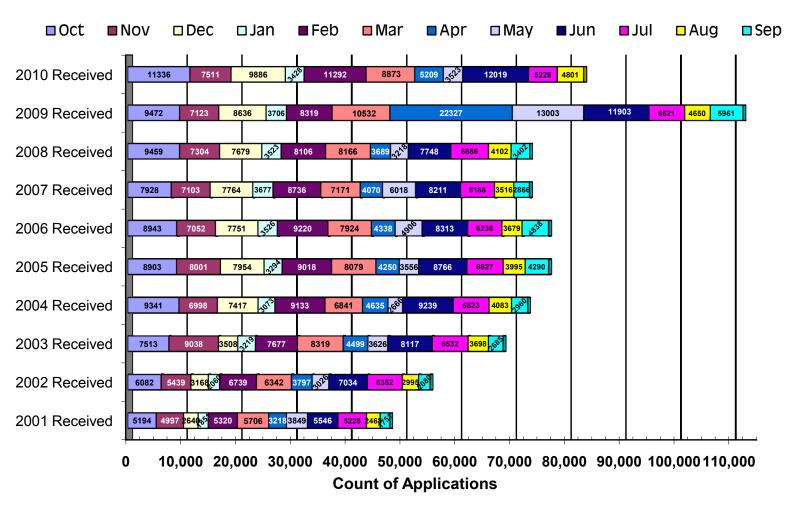


R01 and R21 Received for CSR Review





Application Received By Month of FY



Source:IMPACII - NIH/CSR/OD *Note: numbers reflect date application was received, not assigned or reviewed; File: DRRapps_recvd@CSRFY2010 Revised: 09-08-2010



Enhancing Peer Review

The Study Section Chair as Effective Partner Role and Best Practices

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center for scientific review

National Institutes of Health

U.S. Department of Health and Human Services



Points for Discussion

- 1. The Law (Rules and Regulations)
- 2. Ownership
- 3. The SRO and the Program Officer
- 4. IRG, SRG, Chartered and SEP Study Sections
- 5. Best Practices for Chairs



1. Law, Policies, etc

- Appropriation
- Federal Advisory Committee
- Posting and Advertising
- The Competition
- The Meeting
- The Program Role



2. Ownership

Ownership of the Review

The Process: NIH

• The Science: You and Study Section members

Ownership of the Application

- CSR from receipt to posting of critiques
- Institutes/Program after critiques are posted



3. The SRO and the Program Officer

- The Scientific Review Officer (SRO)
 - 0 240
 - More Senior
 - More Uniformity

Main Role of SRO

- Nomination for Slates and Chair
- Selection of Temporary (ad hoc) Reviewers
- Assignment
- Follow the law, the rules and the regulations

The Program Officer

- Role before and during review
- Conflict
- The Importance of Telephones and Microphones



4. IRG, SRG, Chartered and SEP Study Section

- Integrated Review Group IRG
 - 0 24
 - The legal entity
- Scientific Review Group SRG
 - **1,500**
- Chartered SRGs and Non Chartered SRGs
 - Reasons and Differences
- SEPs
 - Reasons for SEPs
 - Review Outcome
 - Roster of Reviewers and Possible Identification



5. Best Practices of Effective Chairs

- The Assignment of Applications to Chairs
- Before the Meeting
 - Possible Review Problems
 - Posting Critiques by the Deadline
 - No Corridor Discussion and Deals



5. Best Practices of Effective Chairs

During the Meeting

- Impact
- Critique more than Mentoring
- Consistency of Scores
- Consensus should not be forced
- Time Management
- Out of range scoring
- Inappropriate statements
- Do not dominate discussion
- Recap and Summary